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**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Docket Number (Optional)

P-71486-US2

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on \_\_\_\_\_

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Application Number

10/687,336

Filed

October 16, 2003

First Named Inventor

KILCOYNE, John T

Art Unit

3736

Examiner

NGUYEN, HUONG Q

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐

applicant/inventor.

☐

assignee of record of the entire interest.

See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.  
(Form PTO/SB/96)

☒

attorney or agent of record

Registration number 37,912

☐

attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34 \_\_\_\_\_



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Telephone number

November 1, 2011

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

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\*Total of \_\_\_\_\_ forms are submitted.

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): KILCOYNE, John T et al. Examiner: NGUYEN, HUONG Q  
Serial No.: 10/687,336 Group Art Unit: 3736  
Filed: October 16, 2003 Confirmation No.: 7853  
Title: IMPLANTABLE MONITORING PROBE

Mail Stop Appeal  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

**REASONS ACCOMPANYING PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Sir:

This Request for a Pre-Appeal Review Conference is being filed in response to the Final Office Action mailed August 8, 2011 in connection with the above-identified Application, concurrently with a Notice of Appeal and the required fee. A response to the August 8, 2011 Final Office Action ("Final Office Action") is due November 8, 2011. Accordingly, this paper is being timely filed.

In this paper, Applicants identify (1) an omission of essential elements required to establish a *prima facie* rejection and (2) errors in facts in the Final Office Action. No amendments accompany this request.

**REMARKS**

In the Final Office Action, the Examiner rejected claims 50-51 and 58-60 under 35 U.S.C. §103(a) as being unpatentable over Anggiansah et al ("Primary Peristalsis is the Major Acid Clearance Mechanism in Reflux Patients," *Gut* 1994; 35: 1536-1542) in view of Johnsson et al. ("Determinants of Gastroesophageal Reflux and their Inter-relationships," *Br. J. Surg.*, vol. 76, No. 3, pg 241-244, March 1989).

According to the Examiner, Anggiansah discloses a system for measuring physiological parameters in the body of a patient indicative of gastroesophageal reflux, the system comprising a monitoring device, said monitoring device comprising a housing

APPLICANT(S): KILCOYNE, John T et al.  
SERIAL NO.: 10/687,336  
FILED: October 16, 2003  
Page 2

adapted to be implanted in the body of a patient by attachment to tissue inside the body (the Examiner cites to using micropore tape; Anggiansah, pg. 1537 left col.). Final Office Action, p. 3. The Examiner asserts that [www.dictionary.com](http://www.dictionary.com) defines implant as “inserted into the body.” The Examiner further asserts that “[t]he tape used to secure the catheter even if placed *outside* the body nevertheless causes ‘attachment to tissue *inside* the body’,” and notes that the claims do not recite the location and nature of said attachment (See Final Office Action, pp. 8-9; emphasis added).

The Examiner acknowledges on p. 8 of the Final Office Action that Anggiansah does not expressly disclose that the determination of gastroesophageal reflux is based upon both the pH and pressure signals and cites to Johnsson, which, according to the Examiner, teaches that pressure data is highly valuable in gastroesophageal reflux determination and is the single variable that correlates most strongly to the amount of reflux determined using at least pH monitoring.

According to the Examiner, since Johnsson teaches that pressure data is so valuable in the determination of gastroesophageal reflux, it would have been obvious to one of ordinary skill in the art to have the determination of gastroesophageal reflux performed by Anggiansah be made with both pH and pressure signals.

Applicants respectfully disagree with the Examiner’s assertions.

The Examiner cited definition of “implant” as being “to insert into the body” is incomplete, requiring an aspect of fixing or permanence to be complete. The “implant” entry at [dictionary.com](http://dictionary.com) defines the verb implant as (emphasis added):

1. to put or fix **firmly**: to implant sound principles in a child’s mind.
2. to **plant** securely.
3. Medicine/Medical. to insert or graft (a tissue, organ, or inert substance) into the body.

(<http://dictionary.reference.com/browse/implant>) For example, if the Examiner’s definition was complete, a toothbrush while being used or an aspirin tablet while being swallowed would be “implanted”. The Examiner fails to recognize the more complete and thus more accurate definitions, e.g., (A) “to put or fix firmly”; and (B) “to plant securely.” It cannot be said that Anggiansah’s catheters are fixed firmly or planted securely in the patient’s

esophagus because, essentially, Anggiansah's catheters dangle in the esophagus. Applicants note that it may be said that Anggiansah's pH catheter and reference catheter are fixed to the patient's *cheek*, but a patient's cheek is not a "tissue *inside* the body." This difference is not trivial – where the device is implanted affects functionality.

The Examiner seems to ignore Applicants' claim 50 limitation "... implanted in the body of a patient by attachment to tissue *inside* the body," when asserting on page 9 of the Final Office Action that the claims do not recite the location and nature of said attachment. Applicants point out that the claimed location is "*inside* the body" and the nature is "by *attachment to tissue inside* the body."

In maintaining this rejection, the Examiner is essentially saying that "attachment to tissue *outside* the body," is equivalent to "attachment to tissue *inside* the body." Applicants respectfully disagree.

Further, according to the Examiner, Anggiansah's system necessarily contains a housing structure on which said sensors are placed (Final Office Action, pg. 9). Applicants' claim 50 requires "a plurality of sensors including in said housing". Anggiansah's system includes a commercial pH sensing catheter (Synectics Medical, Sweden) and a separate commercial pressure sensing catheter (Gaeltec, Isle of Skye, UK). The two catheters are not placed in a housing, but rather they are *bonded* together for the purpose of the study (see Anggiansah, pg. 1537, right col.). *Bonded* together is not equivalent to *housed* together, and thus Anggiansah does not teach or suggest at least this element of independent claim 50.

In addition, independent claim 50 recites, *inter alia*, "... determines at least the presence of gastroesophageal reflux based on each of said plurality of signals received from said plurality of sensors." Johnsson teaches only that pressure is an important factor in determining the *amount* of reflux, not necessarily the *presence* of reflux. Applicants note further that, in Johnsson, the presence of reflux appears to be determined with a similar sensor as that in Anggiansah; that is, by pH. For example, Figure 1 in Johnsson is the "[r]elation between pressure in the distal oesophageal high pressure zone and percentage of time with pH<4 by pH monitoring." Also in the methods section of Johnsson, on page 241, right column, it is stated that "[t]he amount of gastro-oesophageal reflux was expressed as the percentage of time during the monitoring when pH was <4 in the oesophagus." This is similar

APPLICANT(S): KILCOYNE, John T et al.  
SERIAL NO.: 10/687,336  
FILED: October 16, 2003  
Page 4

to Anggiansah where a "reflux episode was defined as starting when pH fell to less than 4 and ending when the pH rose to 5," (see Anggiansah, Abstract) Thus, as in Anggiansah, Johnsson uses only pH to determine the *presence* of reflux, while pressure is used to correlate the *amount* of reflux.

Applicants note that Johnsson is a study as to what extent various parameters affect the amount of reflux. The Examiner relies merely on a correlation between the pressure in the distal oesophageal high pressure zone and the *amount* of reflux. Applicants note that Johnsson does not teach or suggest anything regarding a correlation between pressure and the *presence* of reflux. As such, Applicants point out that Johnsson does not truly add anything to Anggiansah with respect to determining the presence of gastroesophageal reflux and the combination of Johnsson with Anggiansah does not render independent claim 50 obvious.

Additionally, in Johnsson, pressure is measured in the distal esophageal high pressure zone, whereas in Anggiansah it is measured in various regions of the esophagus. Applicants respectfully assert that the correlation between distal esophageal pressure and amount of reflux in Johnsson is sufficiently different from Anggiansah's measurement of pressure throughout the esophagus, such that a person of skill in the art would not combine the two.

In view of the foregoing, Applicants respectfully assert that independent claim 50 is allowable. Claims 51-60 depend, directly or indirectly, from independent claim 50 and therefore include all the limitations of that claim. Therefore, Applicants respectfully assert that claims 51-60 are likewise allowable. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection to independent claim 50 and to claims 51-60 dependent thereon.

In the Final Office Action, the Examiner rejected claims 52-55 under 35 U.S.C. §103(a) as being unpatentable over Anggiansah in view of Johnsson, and further in view of Brune (U.S. Patent No. 5,984,875) and rejected claims 56-57 under 35 U.S.C. §103(a) as being unpatentable over Anggiansah in view of Johnsson and Brune, and further in view of Kumar et al. (U.S. Patent No. 6,416,471). Applicants respectfully request review of these rejections.

Applicants assert that none of Anggiansah, Johnsson, Brune or Kumar, alone or in combination, teaches or suggests all elements of independent claim 50. Anggiansah and

APPLICANT(S): KILCOYNE, John T et al.  
SERIAL NO.: 10/687,336  
FILED: October 16, 2003  
Page 5

Johnsson have been discussed above with respect to independent claim 50, and that discussion is applicable here. Brune and Kumar are also silent as to "...a housing adapted to be implanted in the body of a patient by attachment to tissue inside the body;" and determining "at least the presence of gastroesophageal reflux based on each of said plurality of signals received from said plurality of sensors," and cannot cure the deficiencies of Anggiansah and Johnsson.

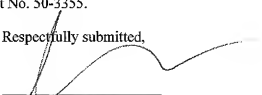
Each of claims 52-55 and 56-57 depends, directly or indirectly, from independent claim 50, and therefore include all the limitations of that claim. Therefore Applicants respectfully assert that claims 52-55 and 56-57 are likewise allowable. Accordingly, Applicants respectfully request that the Examiner withdraw the rejections of claims 52-55 and 56-57 under 35 U.S.C. §103(a).

#### **Conclusion**

In view of the foregoing amendments and remarks, Applicants assert that the pending claims are allowable. Their favorable reconsideration and allowance is respectfully requested. Should the Examiner have any question or comment as to the form, content or entry of this Amendment, or if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

The fee for filing a Notice of Appeal is being filed separately. No other fees are believed due in connection with this paper. However, if any fee is due, please charge any fees associated with this paper to deposit account No. 50-3355.

Respectfully submitted,



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Dated: November 1, 2011

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